Our Docket No.: 00-0220 / 7553.00030

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant:	Stephen J. Brown		
Application No.:	09/496,893	Examiner:	Smith, C.
Filed:	February 2, 2000	Art Group:	1631
For:	SYSTEM AND METHOD FOR IDENTIFYING DISEASE-INFLUENCING GENES		

APPEAL BRIEF

Mail Stop - Appeal Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant submits the following Appeal Brief pursuant to 37 C.F.R. §41.37 for consideration by the Board of Patent Appeals and Interferences. Enclosed herewith is the charge $540.00 to cover the cost of (i) filing the opening brief, as required by 37 C.F.R. §41.20(b)(2). Please charge any additional fees or credit any overpayment to Deposit Account Number 50-0541.

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I. REAL PARTY IN INTEREST

The real parties in interest are Health Hero Network, Inc., the assignee of record and a subsidiary of the Robert Bosch North America, and Abbott Diabetes Care, a subsidiary of Abbott Laboratories, Inc., a licensee of the application.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to the Appellants, Appellants' legal representative, or Assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-82 have been canceled. Claims 83-98 are pending and remain rejected. The Appellants hereby appeal the rejection of claims 83-98.

IV. STATUS OF AMENDMENTS

Appellants are appealing a final Office Action issued by the Examiner on November 14, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

In a first embodiment, represented by independent claim 83, the presently claimed invention provides a method for selecting one or more disease-influencing genes needed to be processed for medical research, comprising (i) selecting individuals having a risk factor for a disease (e.g., elements 400, 500 and 600 in FIGS. 15, 17 and 19, respectively, and page 12, lines 16-24), (ii) providing to each individual a communications apparatus (e.g., element 60 in FIG. 1 and Summary of the Invention), (iii) sending queries to each individual through the apparatus (e.g., elements 402, 502 and 602 in FIGS. 15, 17 and 19, respectively), (iv) receiving responses to the queries from the apparatus (e.g., elements 214 and 312 in FIGS. 11A and 12A, respectively), (v) storing the responses of each individual (e.g., element 312 in FIG. 12A), (vi) defining a plurality of groups by categorizing the individuals having similar profiles based on the responses (e.g., elements 406, 506 and 606 in FIGS. 15, 17 and 19, respectively), (vii) after defining said groups, receiving genotype information for individuals in each of said groups (e.g., elements 414, 514 and 614 in FIGS. 15, 17 and 19, respectively), (viii) comparing said genotype information between said groups (e.g., elements 416 and 516 in FIGS. 16 and 18, respectively) and (ix) generating a report for presentation on a display that represents a subset of said genotype information associated with each of said groups (e.g., elements 418 and 518 in FIGS. 15 and 17, and GENE SEQUENCE A and GENE SEQUENCE B in FIGS. 16 and 18).

In a second embodiment, represented by independent claim 90, the presently claimed invention provides a system (e.g., FIG. 1) for selecting one or more disease-influencing genes needed

to be processed for medical research, comprising (i) a communications apparatus (e.g., 60) operable by an individual (page 16, line 33 through page 17, line 13) and (ii) a communication network (e.g., 58) in signal communication with the communications apparatus (e.g., 60) and a server (e.g., 50), a workstation (e.g., 52) configured to send scripted queries (e.g., FIG. 5, page 20, line 16 through page 21, line 2), a genotyping system (e.g., 56) configured to provide genotype information of the individual (page 30, line 35 through page 31, line 10), and a patient profile system (e.g., 54) configured to receive responses from the individual (e.g., page 30, lines 16-23) and genotype information analyses via the communications network (e.g., 58) and the server (e.g., 52) (e.g., page 30, line 35 through page 31, line 10), whereby the genotype information is compared based upon groups formed using the responses to the scripted queries in the patient profile system to identify one or more individuals having a disease-influencing gene (e.g., page 11, lines 8-19, and page 30, line 35 through page 31, line 10).

In a third embodiment, represented by independent claim 94, the presently claimed invention provides a system (e.g., FIG. 1) for identifying individuals having a disease-influencing gene comprising (a) at least one communications apparatus (e.g., 60) in signal communication with a monitoring device (e.g., 64) configured to measure physiologic and environmental conditions (e.g., page 30, lines 5-14), the communications apparatus (60) and monitoring device (64) being operable by at least one individual (e.g., page 16, line 33 through page 17, line 13) and (b) a communication network (e.g., 58) in signal communications with each communications apparatus (60) and a server (e.g., 50), a workstation (e.g., 52) configured to send scripted queries (e.g., FIG. 5 and page 20, line

16 through page 21, line 2), a genotyping system (e.g., 56) configured to provide genotype information for the at least one individual (e.g., page 30, line 35 through page 31, line 10), and a patient profile system (e.g., 54) configured to receive responses and measurements from the at least one individual (e.g., page 30, lines 16-23) and genotype information analyses via the communications network and the server (e.g., page 30, line 35 through page 31, line 10), whereby the genotype information of the at least one individual is compared based upon groups formed using the responses and measurements to the scripted queries in the patient profile system to identify one or more individuals having a disease-influencing gene (e.g., page 11, lines 8-19, and page 30, line 35 through page 31, line 10).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The first ground of rejection is whether claims 83-98 are unpatentable under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the invention was filed, had possession of the claimed invention.

The second ground of rejection is whether claims 83-98 are unpatentable under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the relevant art to which the claims pertain, or with which the claims are most nearly connected, to make and/or use the claimed invention.

The third ground of rejection is whether claims 83-93 are unpatentable under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

VII. ARGUMENTS

A. 35 U.S.C. §112, First Paragraph, Written Description

As set forth on page 2 of the final Office Action,[1] claims 83-98 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the invention was filed, had possession of the claimed invention. Specifically, the Examiner alleges that there does not appear to be adequate written description for "selecting one or more disease-influencing genes needed to be processed for medical research" (claims 83, 90), "that represents a subset of said genotype information associated with each of said groups" (claim 83), "identifying one or more individuals having a disease-influencing gene" (claim 90), "identifying individuals having a disease-influencing gene" (claim 94), and "to identify one or more individuals having a disease-influencing gene" (claim 94). Claims 83-98 do not stand or fall together. Specifically, claims 83-89 (Group I), claims 90-93 (Group II) and claims 94-98 (Group III) are argued separately.

The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact.[2] A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner

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[1] Mailed November 14, 2008.

[2] Manual of Patent Examining Procedure (M.P.E.P.), Eighth Edition, Rev. 7, July 2008, §2163.04, citing *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

to rebut the presumption.[3] The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in Appellant's disclosure a description of the invention defined by the claims.[4] As explained herein below, because the subject matter contained in the presently pending claims is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the invention was filed, had possession of the claimed invention, claims 83-98 are fully patentable under 35 U.S.C. § 112, first paragraph, and the rejection should be reversed.

1. Claims 83-89 are patentable under 35 U.S.C. §112, First Paragraph

With respect to the rejection of claims 83-89 under 35 U.S.C. §112, first paragraph, as not having adequate written description for the phrases "selecting one or more disease-influencing genes needed to be processed for medical research" and "that represents a subset of said genotype information associated with each of said groups" recited in claim 83, it is not clear whether rejection is based on (i) the Examiner not finding the cited phrases expressly recited in the specification, claims and/or drawings as originally filed or (ii) the Examiner not being able to recognize the support for the phrases in the extensive list of locations provided in the previous response (see page 2, last two lines through page 3, line 3 of the Supplemental Office Action dated November 14, 2008). Both possibilities are addressed by the arguments presented below.

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[3] MPEP §2163.04 citing, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

[4] MPEP §2163.04, citing *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

The specification, claims and/or drawings as originally filed would reasonably convey to a person of ordinary skill in the relevant art that the Appellant, at the time the application was filed, had possession of the presently claimed invention. There is no requirement that the words in the claims must match those used in the specification disclosure (MPEP §2173.05(e)). Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision (MPEP §2173.05(e)). Newly added claim limitations may be supported in the originally filed disclosure through express, implicit, or inherent disclosure (MPEP §2163(B)). By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it (MPEP §2163.07(a)).

A person of ordinary skill in the art relevant to the presently claimed invention would recognize the claims, when read in light of the specification, as containing subject matter which was described in the specification in such a way as to reasonably convey that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, support for the preamble phrase "selecting one or more disease-influencing genes needed to be processed for medical research" can be found, for example, on page 11, lines 8-19 of the specification. In particular, the specification recites:

> Accordingly, it is a primary object of the present invention to provide a system and method for creating a database of information about individuals' environments over a period of time. Another object of the present invention is to provide a database containing information about individuals' environments which can be used with existing genomics databases. **A further object of the present invention is**

> **to provide a method of using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes** or substances. **It is another object of the present invention to use the disease-influencing genes** or substances **to find drug candidates or drug targets** (page 11, lines 8-19 of the specification, emphasis added by Applicant's representative).

A person of ordinary skill in the relevant art would recognize the phrases "find disease-influencing genes" and "use the disease-influencing genes ... to find drug candidates or drug targets" as supporting the phrase "selecting one or more disease-influencing genes needed to be processed for medical research" as recited in claim 83. For example, finding drug candidates or drug targets clearly would be recognized as medical research.

Furthermore, using environmental information and genotype information about individuals having a risk factor for a disease to obtain a group of individuals as part of the medical research for, for example, finding drug candidates or drug targets, could reasonably be described as "selecting one or more disease-influencing genes needed to be processed for medical research." In particular, by selecting particular individuals using genotype information, the selection is related inherently to one or more genes possessed by the individual. As such, written support for the phrase "selecting one or more disease-influencing genes needed to be processed for medical research" as recited in claim 83 is implicitly and/or inherently present in the specification as originally filed.

The Examiner takes the position that:

> While the Figure 17 recites "identify gene" (518) and Figures 8 and 10 show a report for a single patient, these do not provide adequate written support for a display "that represents a subset of said genotype information associated with each of said groups" which differs in scope." Page 3, lines 10-15 of the Supplemental Office Action dated November 14, 2008.

However, a person of ordinary skill in the art relevant to the presently claimed invention would recognize the phrase "that represents a subset of said genotype information associated with each of said groups," recited in claim 83, as containing subject matter which was described in the specification in such a way as to reasonably convey that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, a subset is a portion of a whole (i.e., some part less than the entirety). A person of ordinary skill in the relevant art would recognize the differences between categories (e.g., gene difference in FIGS. 15 and 17, GENE SEQUENCE A and GENE SEQUENCE B in FIGS. 16, 18 and 20, etc.) found when comparing the genotype information of individuals between groups could reasonably be referred to as a subset of the total genotype information associated with the individuals and the groups.

A region of a gene sequence would also reasonably be referred to as a subset of the gene sequence. For example, written support for the phrases "selecting one or more disease-influencing genes needed to be processed for medical research" (e.g., isolating the relevant genes) and "that represents a subset of the genotype information" (e.g., identify certain regions of the genome which appear to be associated with the disease) can also be found in the paragraph on page 5, lines 5-15 of the specification. The Examiner contends that the passage on page 5 does not provide adequate written support for the two phrases because "selecting" genes and "isolating" genes are not similar in definition (page 4, lines 6-17 of the Supplemental Office Action dated November 14, 2008). The Examiner goes on to state that selecting and isolating are two separate concepts and actions. In particular, the Examiner states that a "selecting" scenario is, for example, having three possible options of genes on a computer screen and the user choosing one of the options.

Meanwhile, the "isolating" genes scenario, for example, involves physical laboratory steps to separate genes from another substance so as to obtain a pure state. The Examiner has not provided objective evidence or authority supporting the statement that "selecting" and "isolating" are two different concepts and actions (see, e.g., page 4, line 18 of the Supplemental Office Action dated November 14, 2008).

In contrast to the Examiner's position, the definition for the term "isolating" found in the Merriam-Webster Online Dictionary states that isolating is an inflected form of isolate. The definition of the term "isolate" includes "**to select** from among others" (see definition of isolate, Merriam-Webster Online Dictionary, http://www.merriam-webster.com/dictionary/isolating). Thus, the concept and action of isolating would appear to include the concept and action of selecting. As such, the definitions used by the Office appear to be overly narrow rather than reasonably broad, and the arguments made against the written description support for the claim language does not appear to be appropriately based upon objective authority.

A further example provided in the specification as originally filed, which provides support for the term subset, is the use of data mining techniques to find differences in gene sequences (see page 31, lines 1-10 of the specification). Differences in gene sequences between groups is inherently a subset of the set comprising the entire gene sequences. A report of the results of the data mining (e.g., differences in individual gene sequences A and B between groups) would be presented (e.g., displayed, printed, etc.) or else the data mining would not be useful or advantageous. Furthermore, in connection with FIGS. 2 and 10, the specification states that specific techniques for writing a report generator program to display data are well known in the software art (e.g., see page

24, lines 12-21 of the specification as originally filed). As such, the specification as originally filed would reasonably convey to a person of ordinary skill in the relevant art that the Appellant, at the time the application was filed, had possession of the presently claimed invention and the rejection should be reversed.

Furthermore, page 11, lines 13-17 of the specification state that "A further object of the present invention is to provide a method of using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes or substances." The Examiner states that to find and to select are not commensurate in scope as "find" **may indicate** that the information was not previously known, while "select" **can be interpreted**, for example, to be a user action of deciding which genes from an already verified list to choose (page 5, lines 7-17 of the Supplemental Office Action dated November 14, 2008). However, the Examiner has not provided any analysis why the particular interpretations for "find" and "select" are considered reasonable when read in light of the specification and what other meanings the terms "find" and "select" might also have been be interpreted to have.

The Examiner further notes "that "to be processed for medical research" and "to use the disease-influencing genes or substances to find drug candidates or drug targets" are not commensurate in scope as the first mention phrase is broader. Processed for medical research encompasses activities such as clinical trials, developing pharmaceuticals and kits, diagnosing disease, etc. which is broader than just finding drug candidates or targets." However, the specification states that "The system and method of the invention have many other applications. For example, pharmaceutical manufactures may apply the system in clinical trials to analyze new drug

data." (page 36, lines 2-5 of the specification). Thus, accepting the Examiner's interpretation that the phrase "processed for medical research" encompasses activities such as clinical trials, developing pharmaceuticals and kits, diagnosing disease, etc., the specification provides written support for the broader scope.

For the reasons presented above, the phrases "selecting one or more disease-influencing genes needed to be processed for medical research" and "that represents a subset of said genotype information associated with each of said groups," as recited in claim 83, have written support in the specification, claims and/or drawings as originally filed and, therefore, do not constitute new matter. As such, the rejection under 35 U.S.C. §112, first paragraph with respect to the "written description" requirement does not appear to be sustainable and should be reversed.

2. Claim 90-93 is patentable under 35 U.S.C. §112, First Paragraph

With respect to the rejection of claims 90-93 under 35 U.S.C. §112, first paragraph, as not having adequate written description for the phrases "selecting one or more disease-influencing genes needed to be processed for medical research" and "to identify one or more individuals having a disease-influencing gene" recited in claim 90, it is not clear whether rejection is based on (i) the Examiner not finding the cited phrases expressly recited in the specification, claims and/or drawings as originally filed or (ii) the Examiner not being able to recognize the support for the phrases in the extensive list of locations provided in the previous response (see page 2, last two lines through page 3, line 3 of the Supplemental Office Action dated November 14, 2008). Both possibilities are addressed by the arguments presented below.

The specification, claims and/or drawings as originally filed would reasonably convey to a person of ordinary skill in the relevant art that the Appellant, at the time the application was filed, had possession of the presently claimed invention. There is no requirement that the words in the claims must match those used in the specification disclosure (MPEP §2173.05(e)). Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision (MPEP §2173.05(e)). Newly added claim limitations may be supported in the originally filed disclosure through express, implicit, or inherent disclosure (MPEP §2163(B)). By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it (MPEP §2163.07(a)).

A person of ordinary skill in the art relevant to the presently claimed invention would recognize the claims, when read in light of the specification, as containing subject matter which was described in the specification in such a way as to reasonably convey that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, support for the preamble phrase "selecting one or more disease-influencing genes needed to be processed for medical research" can be found, for example, on page 11, lines 8-19 of the specification. In particular, the specification recites:

> Accordingly, it is a primary object of the present invention to provide a system and method for creating a database of information about individuals' environments over a period of time. Another object of the present invention is to provide a database containing information about individuals' environments which can be used with existing genomics databases. **A further object of the present invention is**

> **to provide a method of using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes** or substances. **It is another object of the present invention to use the disease-influencing genes** or substances **to find drug candidates or drug targets** (page 11, lines 8-19 of the specification, emphasis added by Applicant's representative).

A person of ordinary skill in the relevant art would recognize the phrases "find disease-influencing genes" and "use the disease-influencing genes ... to find drug candidates or drug targets" as supporting the phrase "selecting one or more disease-influencing genes needed to be processed for medical research" as recited in claim 90. For example, finding drug candidates or drug targets clearly would be recognized as medical research.

Furthermore, using environmental information and genotype information about individuals having a risk factor for a disease to obtain a group of individuals as part of the medical research for, for example, finding drug candidates or drug targets, could reasonably be described as "selecting one or more disease-influencing genes needed to be processed for medical research." In particular, by selecting particular individuals using genotype information, the selection is related inherently to one or more genes possessed by the individual. As such, written support for the phrase "selecting one or more disease-influencing genes needed to be processed for medical research" as recited in claim 90 is implicitly and/or inherently present in the specification as originally filed.

Written support for the phrase "selecting one or more disease-influencing genes needed to be processed for medical research" (e.g., isolating the relevant genes) can also be found in the paragraph on page 5, lines 5-15 of the specification. The Examiner contends that the passage on page 5 does not provide adequate written support for the phrase because "selecting" genes and

"isolating" genes are not similar in definition (page 4, lines 6-17 of the Supplemental Office Action dated November 14, 2008). The Examiner goes on to state that selecting and isolating are two separate concepts and actions. In particular, the Examiner states that a "selecting" scenario is, for example, having three possible options of genes on a computer screen and the user choosing one of the options. Meanwhile, the "isolating" genes scenario, for example, involves physical laboratory steps to separate genes from another substance so as to obtain a pure state. The Examiner has not provided objective evidence or authority supporting the statement that "selecting" and "isolating" are two different concepts and actions (see, e.g., page 4, line 18 of the Supplemental Office Action dated November 14, 2008).

In contrast to the Examiner's position, the definition for the term "isolating" found in the Merriam-Webster Online Dictionary states that isolating is an inflected form of isolate. The definition of the term "isolate" includes "**to select** from among others" (see definition of isolate, Merriam-Webster Online Dictionary, http://www.merriam-webster.com/dictionary/isolating). Thus, the concept and action of isolating would appear to include the concept and action of selecting. As such, the definitions used by the Office appear to be overly narrow rather than reasonably broad, and the arguments made against the written description support for the claim language does not appear to be appropriately based upon objective authority.

Furthermore, page 11, lines 13-17 of the specification state that "A further object of the present invention is to provide a method of using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes or substances." The Examiner states that to find and to select are not commensurate in scope as "find" **may indicate** that

the information was not previously known, while "select" **can be interpreted**, for example, to be a user action of deciding which genes from an already verified list to choose (page 5, lines 7-17 of the Supplemental Office Action dated November 14, 2008). However, the Examiner has not provided any analysis why the particular interpretations for "find" and "select" are considered reasonable when read in light of the specification and what other meanings the terms "find" and "select" might also have been interpreted to have.

The Examiner further notes "that "to be processed for medical research" and "to use the disease-influencing genes or substances to find drug candidates or drug targets" are not commensurate in scope as the first mentioned phrase is broader. Processed for medical research encompasses activities such as clinical trials, developing pharmaceuticals and kits, diagnosing disease, etc. which is broader than just finding drug candidates or targets." However, the specification states that "The system and method of the invention have many other applications. For example, pharmaceutical manufactures may apply the system in clinical trials to analyze new drug data." (page 36, lines 2-5 of the specification). Thus, accepting the Examiner's interpretation that the phrase "processed for medical research" encompasses activities such as clinical trials, developing pharmaceuticals and kits, diagnosing disease, etc., the specification provides written support for the broader scope.

Furthermore, a person of ordinary skill in the relevant art would also recognize the phrase "using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes" as supporting the phrase "to identify one or more individuals having a disease-influencing gene" as recited in claim 90. It is inherent that if disease-

influencing genes are found using individual's genotype information, the individuals having the disease-influencing genes have been identified. Further support for the phrase "to identify one or more individuals having a disease-influencing gene" as recited in claim 90 can be found on page 31, line 27 through page 32, line 2 of the specification as originally filed. As such, the specification as originally filed would reasonably convey to a person of ordinary skill in the relevant art that the Appellant, at the time the application was filed, had possession of the presently claimed invention and the rejection should be reversed.

For the reasons presented above, the phrases "selecting one or more disease-influencing genes needed to be processed for medical research" and "to identify one or more individuals having a disease-influencing gene," as recited in claim 90, have written support in the specification, claims and/or drawings as originally filed and, therefore, do not constitute new matter. As such, the rejection under 35 U.S.C. §112, first paragraph with respect to the "written description" requirement does not appear to be sustainable and should be reversed.

3. Claim 94-98 is patentable under 35 U.S.C. §112, First Paragraph

With respect to the rejection of claims 94-98 under 35 U.S.C. §112, first paragraph, as not having adequate written description for the phrases "identifying individuals having a disease-influencing gene" and "to identify one or more individuals having a disease-influencing gene" recited in claim 94, it is not clear whether rejection is based on (i) the Examiner not finding the cited phrases expressly recited in the specification, claims and/or drawings as originally filed or (ii) the Examiner not being able to recognize the support for the phrases in the extensive list of locations

provided in the previous response (see page 2, last two lines through page 3, line 3 of the Supplemental Office Action dated November 14, 2008). Both possibilities are addressed by the arguments presented below.

The specification, claims and/or drawings as originally filed would reasonably convey to a person of ordinary skill in the relevant art that the Appellant, at the time the application was filed, had possession of the presently claimed invention. There is no requirement that the words in the claims must match those used in the specification disclosure (MPEP §2173.05(e)). Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision (MPEP §2173.05(e)). Newly added claim limitations may be supported in the originally filed disclosure through express, implicit, or inherent disclosure (MPEP §2163(B)). By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it (MPEP §2163.07(a)).

A person of ordinary skill in the relevant art would recognize the phrase "using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes" as supporting the phrase "to identify one or more individuals having a disease-influencing gene" as recited in claim 94. It is inherent that if disease-influencing genes are found using individual's genotype information, the individuals having the disease-influencing genes have been identified. Further support for the phrase "to identify one or more individuals having a disease-influencing gene" as recited in claim 94 can be found on page 31, line 27 through page 32,

line 2 of the specification as originally filed. As such, the specification as originally filed would reasonably convey to a person of ordinary skill in the relevant art that the Applicant, at the time the application was filed, had possession of the presently claimed invention and the rejection should be reversed.

For the reasons presented above, the phrases "identifying individuals having a disease-influencing gene" and "to identify one or more individuals having a disease-influencing gene," as recited in claim 94, have written support in the specification, claims and/or drawings as originally filed and, therefore, do not constitute new matter. As such, the rejection under 35 U.S.C. §112, first paragraph with respect to the "written description" requirement does not appear to be sustainable and should be reversed.

B. <u>35 U.S.C. §112, First Paragraph, Enablement</u>

As set forth on page 7 of the final Office Action,[5] claims 83-98 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the relevant art to which the claims pertain, or with which the claims are most nearly connected, to make and/or use the claimed invention. Claims 83-98 do not stand or fall together. Specifically, claims 83-89 (Group I), claims 90-93 (Group II) and claims 94-98 (Group III) are argued separately.

The examiner has the initial burden to establish a reasonable basis to question the

[5] Mailed November 14, 2008.

enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. As explained herein below, because the specification disclosure contains a teaching of the manner and process of making and using the presently claimed invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented, claims 83-98 are fully patentable under 35 U.S.C. § 112, first paragraph, and the rejection should be reversed.

1. Claim 83-89 are patentable under 35 U.S.C. §112, First Paragraph

Independent claim 83 provides a method for selecting one or more disease-influencing genes needed to be processed for medical research. The method comprises (i) selecting individuals having a risk factor for a disease, (ii) providing to each individual a communications apparatus, (iii) sending queries to each individual through the apparatus, (iv) receiving responses to the queries from the apparatus, (v) storing the responses of each individual, (vi) defining a plurality of groups by categorizing the individuals having similar profiles based on the responses, (vii) after defining said groups, receiving genotype information for individuals in each of said groups, (viii)

comparing the genotype information between the groups and (ix) generating a report for presentation on a display that represents a subset of the genotype information associated with each of the groups. The subject matter of the presently pending claims 83-89 was described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most connected, to make and/or use the claimed invention. As such, claims 83-89 are fully patentable under 35 U.S.C. § 112, first paragraph, and the rejection should be reversed.

The Examiner states that Appellant's invention is directed to the clustering of individuals into groups based on responses to queries and then determining gene differences between groups in order to determine gene differences for selecting disease-influencing genes or identifying individuals having a disease-influencing gene (see page 8, lines 2-5 of the Supplemental Office Action dated November 14, 2008). The Examiner alleges that because determining gene differences between the groups involves complications which would result in an unpredictable length and difficulty in a research project that simply clusters individuals via queries regarding the behavior or other characteristics to then isolate or focus on one or more disease-influencing gene(s), the instant claims lack enablement (page 8, line 5 through page 9, line 3 of the Supplemental Office Action dated November 14, 2008). However, claim 83 does not recite clustering of individuals into groups based on responses to queries and then determining gene differences between groups in order to determine gene differences for selecting disease-influencing genes or identifying individuals having a disease-influencing gene. Rather, claim 83 recites (vii) after defining the groups, receiving genotype information for individuals in each of the groups, (viii) comparing the genotype information between the groups and (ix) generating a report for presentation on a display that

represents a subset of the genotype information associated with each of the groups. The specification discloses a genotyping system 56 for providing genotype information (see FIGS. 1 and 2 of the specification). The specification states that the genotyping system 56 can be a laboratory capable of sequencing individual's genomes, a gene sequencing chip such as the GeneChip by Affymetrix, or any other suitable genotyping system (page 16, lines 4-6 of the specification. Thus, the specification clearly provides information which would enable the skilled artisan to practice the step of (vii) after defining the groups, receiving genotype information for individuals in each of the groups (e.g., by using a gene sequencing chip such as the GeneChip by Affymetrix). The specification also states that data mining techniques are used to compare the genotype information of the individuals between categories (see, e.g., page 31, lines 1-3 of the specification). Thus, the specification clearly provides information which would enable the skilled artisan to practice the step of (viii) comparing the genotype information between the groups. Furthermore, the skilled artisan is just that, skilled. A person of ordinary skill in the relevant art would understand that a subset of the genotype information associated with each of the groups represents some portion of the genotype information (e.g., specific difference or similarities between groups, etc.) that is less than the entire amount of information received. The specification also states that specific techniques for writing a report generator program to display data are well known in the software art. Thus, the specification clearly supports that no undue experimentation would be involved in order for the skilled artisan to practice the step of (ix) generating a report for presentation on a display that represents a subset of the genotype information associated with each of the groups. As such, claims 83-89 are fully patentable under 35 U.S.C. § 112, first paragraph, and the rejection should be reversed.

2. Claims 90-93 are patentable under 35 U.S.C. §112, First Paragraph

Independent claim 90 recites limitations similar to claim 83 and is rejected for the same reason as claim 83. Therefore, the arguments presented above in support of claim 83 are herein incorporated by reference in support of claim 90. As such, claims 90-93 are fully patentable under 35 U.S.C. § 112, first paragraph, and the rejection should be reversed.

3. Claim 94-98 are patentable under 35 U.S.C. §112, First Paragraph

Independent claim 94 recites limitations similar to claim 83 and is rejected for the same reason as claim 83. Therefore, the arguments presented above in support of claim 83 are herein incorporated by reference in support of claim 94. As such, claims 94-98 are fully patentable under 35 U.S.C. § 112, first paragraph, and the rejection should be reversed.

C. 35 U.S.C. §112, Second Paragraph

As set forth on page 12 of the final Office Action,[6] claims 83-93 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 83-98 do not stand or fall together. Specifically, claims 83-89 (Group I) and claims 90-93 (Group II) are argued separately.

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[6] Mailed November 14, 2008.

Claims 83 and 90 would apprise one of ordinary skill in the art of their scope and, therefore, serve the notice function required by 35 U.S.C. 112, paragraph 2. As such, the rejections of claims 83-93 under 35 U.S.C. § 112, second paragraph, do no appear to be sustainable and should be reversed.

1. Claims 83-89 are patentable under 35 U.S.C. §112, Second Paragraph

With respect to the rejection of claims 83-89 under 35 U.S.C. §112, second paragraph, as being indefinite, claims 83 and 90 would apprise one of ordinary skill in the art of their scope and, therefore, serve the notice function required by 35 U.S.C. 112, second paragraph.

The Examiner states:

> The preamble of claim 83 recites selecting one or more disease-influencing genes whereas the body of the claim recites selecting individuals, but not genes. In addition, the body of the claim recites generating a report representing a subset of genotype information, which is not necessarily one or more disease-influencing genes. Therefore, it is not clear if the preamble is intended to limit the method and what relationship is intended between the preamble and method steps. Claims 84-89 are also rejected due to their dependency from claim 83. Page 12, last four lines through page 13, line 2 of the Supplemental Office Action dated November 14, 2008).

The preamble of claim 83 recites "A method for selecting one or more disease-influencing genes needed to be processed for medical research." The mere fact that the body of a claim recites elements which do not appear in the claim's preamble does not render the claim indefinite under 35 U.S.C. 112, second paragraph (MPEP §2173.05(e)). If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed

invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. MPEP §2111.02(II) citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"). The body of claim 83 fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations. Therefore, the preamble should be not considered a limitation on the method. As such, claims 83-89 are believed to be definite within the meaning of 35 USC §112, second paragraph, and the rejection should be reversed.

2. Claims 90-93 is patentable under 35 U.S.C. §112, Second Paragraph

With respect to the rejection of claims 90-93 under 35 U.S.C. §112, second paragraph, as being indefinite, claim 90-93 would apprise one of ordinary skill in the art of their scope and, therefore, serve the notice function required by 35 U.S.C. 112, second paragraph.

The Examiner states:

> The preamble of claim 90 recites selecting one or more disease-influencing genes whereas the body of the claim recites selecting individuals, but not genes. In addition, the body of the claim recites generating a report representing a subset of genotype information, which is not necessarily one or more disease-influencing genes. Therefore, it is not clear if the preamble is intended to limit the method and what relationship is intended between the preamble and method steps. Claims 91-93 are also rejected due to their dependency

from claim 83. Page 13, lines 3-7 of the Supplemental Office Action dated November 14, 2008).

The preamble of claim 90 recites "A system for selecting one or more disease-influencing genes needed to be processed for medical research." The mere fact that the body of a claim recites elements which do not appear in the claim's preamble does not render the claim indefinite under 35 U.S.C. 112, second paragraph (MPEP §2173.05(e)). If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. MPEP §2111.02(II) citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"). The body of claim 90 fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations. Therefore, the preamble should be not considered a limitation on the method. As such, claims 90-93 are believed to be definite within the meaning of 35 USC §112, second paragraph, and the rejection should be reversed.

D. CONCLUSION

Claims 83-98 are fully patentable under 35 U.S.C. §112. Hence, the Examiner has clearly erred with respect to the patentability of the claimed invention. It is respectfully requested that the Board overturn the Examiner's rejection of all pending claims, and hold that the claims are definite and fully supported by the specification.

Respectfully submitted,

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Christopher P. Maiorana
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Dated: April 10, 2009

c/o Sandeep Jaggi
Health Hero Network

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VIII. CLAIM APPENDIX

The claims of the present application which are involved in this appeal are as follows:

1-82. (CANCELED).

83. A method for selecting one or more disease-influencing genes needed to be processed for medical research, comprising:

selecting individuals having a risk factor for a disease;

providing to each individual a communications apparatus;

sending queries to each individual through the apparatus;

receiving responses to the queries from the apparatus;

storing the responses of each individual;

defining a plurality of groups by categorizing the individuals having similar profiles based on the responses;

after defining said groups, receiving genotype information for individuals in each of said groups;

comparing said genotype information between said groups; and

generating a report for presentation on a display that represents a subset of said genotype information associated with each of said groups.

84. The method of Claim 83, wherein the queries are script-based and are assignable to each individual.

85. The method of Claim 84, wherein the queries are inserted into a script program with a script generator and assigned to an individual using a script assignor.

86. The method of Claim 83, wherein categorizing the individuals into groups includes one of the phenotypic classifications from the set of behavioral, environmental, and disease progression.

87. The method of Claim 86 wherein differences in said genotype information between said groups is expressed by genetic expression among the phenotypic classifications.

88. The method of claim 83, wherein the communication apparatus is connectable with a monitoring device configured to acquire physiologic data.

89. The method of claim 88, wherein the monitoring device includes one of the set consisting of a blood glucose meter, a respiratory flow meter, a blood pressure cuff, a weight scale, and a pulse rate monitor.

90. A system for selecting one or more disease-influencing genes needed to be processed for medical research, comprising:

a communications apparatus operable by an individual; and

a communication network in signal communication with the communications apparatus and a server, a workstation configured to send scripted queries, a genotyping system configured to provide genotype information of the individual, and a patient profile system configured to receive responses from the individual and genotype information analyses via the communications network and the server,

whereby the genotype information is compared based upon groups formed using the responses to the scripted queries in the patient profile system to identify one or more individuals having a disease-influencing gene.

91. The system of Claim 90, wherein the scripted queries are generated for the individual using a script generator and assigned to the individual using a script assignor.

92. The system of Claim 90, wherein the responses from the individual are used to categorize the individual into one or more groups and the one or more groups are compared with the genotype information of the individual to categorize said genotype information according to disease progression.

93. The system of Claim 92, wherein the disease progression includes non-insulin dependent diabetes.

94. A system for identifying individuals having a disease-influencing gene comprising:

at least one communications apparatus in signal communication with a monitoring device configured to measure physiologic and environmental conditions, the communications apparatus and monitoring device being operable by at least one individual; and

a communication network in signal communications with each communications apparatus and a server, a workstation configured to send scripted queries, a genotyping system configured to provide genotype information for the at least one individual, and a patient profile system configured to receive responses and measurements from the at least one individual and genotype information analyses via the communications network and the server,

whereby the genotype information of the at least one individual is compared based upon groups formed using the responses and measurements to the scripted queries in the patient profile system to identify one or more individuals having a disease-influencing gene.

95. The system of Claim 94, wherein the scripted queries are generated for each individual using a script generator and assigned to each individual using a script assignor.

96. The system of Claim 94, wherein the monitoring device includes one of the set consisting of a blood glucose meter, a respiratory flow meter, a blood pressure cuff, a weight scale, and a pulse rate monitor.

97. The system of Claim 94, wherein the responses and measurements from each individual are used to categorized each individual with one or more groups and the groups are compared with the genotype information of each individual to categorize the genotype information according to disease progression of each individual in the one or more groups based on the responses and measurements sent by each individual.

98. The system of Claim 97, wherein the disease progression includes non-insulin dependent diabetes.

IX. EVIDENCE APPENDIX

1. NIH News Release: Human Chromosome 22: First to be Decoded, dated December 19, 1999, Human Genome Project Information, pages 1-3. Submitted as Exhibit A with a Response After Final filed November 27, 2007; entered December 17, 2007.

[redacted]

Human Chromosome 22: First to be Decoded

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December 1, 1999

Scientists complete first chapter of book of life with decoding of chromosome 22

An international team of researchers has achieved a scientific milestone by unraveling for the first time the genetic code of an entire human chromosome.

Reported in this week's issue of Nature (Dec. 2), researchers at the Sanger Centre near Cambridge, England; University of Oklahoma, Norman, OK; Washington University, St. Louis, MO; and Keio University in Japan have succeeded in deciphering the sequence of the 33.5 million "letters," or chemical components, that make up the DNA of chromosome 22.

This sequence includes the longest, continuous stretch of DNA ever deciphered and assembled. It is over 23 million letters in length.

Each human gene is made up of a series of chemical building blocks represented by letters, A (adenine), T (thymine), G (guanine) and C (cytosine). The number and order of these letters, also called bases, determine what we are, how we look, and the diseases to which we may be predisposed. The chromosome 22 team has deduced the text of one chapter of the human genetic instruction book.

The next mammoth task is to determine what it all means. Sequencing and mapping efforts have already revealed that chromosome 22 is implicated in the workings of the immune system, congenital heart disease, schizophrenia, mental retardation, birth defects, and several cancers including leukemia. But, the scientific team agrees that many more secrets are to be discovered in this decoded text.

The sequencing of chromosome 22 permits scientists for the first time to view the entire DNA of a chromosome.

"This is the first time that we have been able to see the organization of a chromosome at the base pair level," said Dr. Ian Dunham, senior research fellow at the Sanger Centre and leader of the research team that deciphered chromosome 22. "This immediately suggests new experiments and avenues of research which can be pursued."

"To see the entire sequence of a human chromosome for the first time is like seeing an ocean liner emerge out of the fog, when all you've ever seen before were rowboats," said Dr. Francis Collins, director of the National Human Genome Research Institute of the National Institutes of Health which supported the U.S. contribution to the sequencing of chromosome 22.

University of Oklahoma scientist Dr. Bruce Roe, one of the researchers who deciphered the sequence of chromosome 22, added, "It's incredible. For the first time we can stand back and view a picture of all the structures and other features of a human chromosome, to see how a chromosome is organized. Now we can begin to understand where genes are located on chromosomes, how they express themselves, how deletions that give rise to disease-causing mutations occur, and how chromosomes are duplicated and inherited."

Chromosome 22 is the first of 23 human chromosome pairs to be deciphered because of its relatively small size and its association with several diseases and because of the groundwork of several scientists beginning in the early 1990s.

Because protein-coding genes do not seem to occur on the short arm of chromosome 22, the scientists focused on the chromosome's long arm, which is richer in genes relative to other human chromosomes. Ninety seven percent of this arm was sequenced.

The sequence contains 11 gaps or areas that could not be deciphered with current technology. The location and size of the gaps were determined. The 33.5 million bases of sequenced DNA are extremely high quality with an error rate of less than one in 50,000 bases.

- Sequencing
- Instrumentation
- Mapping
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- Functional Genomics
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The sequence reveals the following about the landscape of chromosome 22:

- A total number of at least 545 genes and 134 pseudogenes (genes that once functioned but no longer do) were detected on the chromosome, with 200 to 300 additional ones likely. If representative of other chromosomes, this count suggests that the total number of genes on all human chromosomes will not be substantially more or less than the previously estimated number of 80,000.
- The genes range in size from 1,000 to 583,000 bases of DNA with a mean size of 190,000 bases. A total of 39 percent of the chromosome is copied into RNA (exons and introns), while only 3 percent of the chromosome encodes protein.
- A total of 247 genes were revealed by computer analyses to be identical to previously identified human genes or protein sequences. Computer analysis of the chromosome 22 sequence found 150 additional genes with DNA sequence similarity to known genes. An additional 148 predicted genes containing sequence homologous to known genetic markers (ESTs) were identified.
- Several gene families appear to have arisen by tandem duplication. There are families of genes that are interspersed among other genes and distributed over large chromosomal regions.
- There is unexpected long-range complexity of the chromosome with an elaborate array of repeat sequences near the centromere of the chromosome. The existence of so much repetitive DNA information could help explain how this chromosome rearranges or reshuffles its DNA, leading to human disorders such as DiGeorge syndrome, which includes a form of mental retardation, and how chromosome structure changes over time.
- An unexpected finding shows several regions where recombination is increased, and others where it is suppressed, and these will probably play a role in health and disease.

Comparing the chromosome 22 sequence to known gene sequences of the mouse, a lab animal frequently used to facilitate understanding of human genetic disorders, the research team found 160 human genes that have comparable sequences in the mouse. Examining the chromosomal locations of the mouse genes that have counterparts on the human chromosome 22 shows that the order of the genes along the chromosome in the two species is genetically conserved, although the mouse homologs of human genes on chromosome 22 are dispersed to eight different mouse chromosomal regions.

The sequencing of the DNA of chromosome 22 was conducted as part of the international Human Genome Project, which involves scientists in the U.S., England, Japan, France, Germany and China.

In deciphering chromosome 22, scientists used the approach that has been developed and widely tested by the Human Genome Project. This approach involves sequencing overlapping cloned segments of DNA from known locations on the chromosome.

Until now, scientists were uncertain about whether an entire human chromosome could be sequenced in this manner. For example, they did not know whether insurmountable problems would prevent assembling their sequencing data. The presence of a small number of unclonable gaps was not unexpected, but the scientists carrying out this project adhered to the agreed upon standard that a chromosome should not be considered "essentially complete," until the sequence of regions that are clonable and sequenceable with current technology have been determined to high accuracy, and the sizes of any remaining gaps have been determined.

"That chromosome 22 was essentially sequenced by using overlapping clones increases our confidence that the Human Genome Project will be able to complete a 'working draft' of the DNA sequence of the human genome in Spring 2000 and finish it by 2003," said Dr. Richard Wilson, co-director of the Genome Sequencing Center at Washington University School of Medicine in St. Louis and member of the research team that deciphered chromosome 22.

The results of the Human Genome Project, which are freely accessible through public databases such as GenBank (www.ncbi.nlm.nih.gov/genome/seq), give scientists insight into the way genes are arranged along a strip of DNA and paves the way for major advances in the diagnosis and treatment of disease.

Knowing the identity and order of the chemical components of the DNA of the 23 pairs of chromosomes that are found in almost every human cell provides a tool to determine the basis of health and disease. "The fact that all of this information is now freely available for scientists to use, without the constraints of patents and fees, is of major importance, if the knowledge of our genetic make-up is to be used for the good of mankind," said Dr. Michael Morgan, chief executive of the Wellcome Trust Genome Campus, which is home to the Sanger Centre.

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X. RELATED PROCEEDINGS APPENDIX

None.